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NEWS PHONE Direct Dial and Telecommunication Network Access to STN
NEWS WWW CAS World Wide Web Site (general information)

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=> file caplus medline biosis embase uspatfull
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FULL ESTIMATED COST

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=> s (ethinyl estradiol) and norelgestromin L1 109 (ETHINYL ESTRADIOL) AND NORELGESTROMIN

=> 11 dup rem

L1 IS NOT A RECOGNIZED COMMAND

The previous command name entered was not recognized by the system. For a list of commands available to you in the current file, enter "HELP COMMANDS" at an arrow prompt (=>).

=> dup rem l1
PROCESSING COMPLETED FOR L1

L2 61 DUP REM L1 (48 DUPLICATES REMOVED)

=> 12 and contraception

L2 IS NOT A RECOGNIZED COMMAND

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=> s 12 and contraception

L3 36 L2 AND CONTRACEPTION

=> d ibib abs 13 1-10

L3 ANSWER 1 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN

ACCESSION NUMBER: 2005:1201071 CAPLUS

DOCUMENT NUMBER:

143:416738

TITLE:

Management of breakthrough bleeding in extended hormonal contraceptive regimens and use of the contraceptives in treating other gynecological

disorders

INVENTOR(S):

Sachse, Andreas

PATENT ASSIGNEE(S):

Schering Aktiengesellschaft, Germany

SOURCE:

PCT Int. Appl., 19 pp.

CODEN: PIXXD2

DOCUMENT TYPE:

Patent English

LANGUAGE:

Eng.

FAMILY ACC. NUM. COUNT:

PATENT INFORMATION:

	PATENT NO.				KIND DATE			APPLICATION NO.					DATE					
	WO 2005105103			A2 20051110			WO 2005-EP4777				20050429							
		W:	ΑE,	AG,	AL,	AM,	AT,	ΑU,	ΑZ,	BA,	BB,	BG,	BR,	BW,	BY,	BZ,	CA,	CH,
			CN,	co,	CR,	CU,	CZ,	DE,	DK,	DM,	DZ,	EC,	EE,	EG,	ES,	FI,	GB,	GD,
			GE,	GH,	GM,	HR,	ΗU,	ID,	IL,	IN,	IS,	JP,	KE,	KG,	KM,	KP,	KR,	ΚZ,
			LC,	LK,	LR,	LS,	LT,	LU,	LV,	MA,	MD,	MG,	MK,	MN,	MW,	MX,	MZ,	NA,
			NI,	NO,	NZ,	OM,	PG,	PH,	PL,	PT,	RO,	RU,	SC,	SD,	SE,	SG,	SK,	SL,
								TR,										
			ZM,	zw														
		RW:	BW,	GH,	GM,	ΚE,	LS,	MW,	MZ,	NA,	SD,	SL,	SZ,	TZ,	ŪĠ,	ZM,	ZW,	AM,
			AZ,	BY,	KG,	ΚZ,	MD,	RU,	ТJ,	TM,	AT,	BE,	BG,	CH,	CY,	CZ,	DE,	DK,
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										1	US 2	004-	5750	24P]	P 2	0040	528
										1	US 2	004-	5771	99P]	P 2	0040	607
											US 2	004-	6383	30P]	P 2	0041	227
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AB The present invention relates to a flexible extended use regimen for a hormonal (estrogen/progestin combination) contraceptive useful to manage bleeding problems associated with fixed extended use of hormonal contraceptives and to a pharmaceutical package containing the resp. hormonal contraceptive. Specifically claimed is a method for female hormonal contraception which comprises the monophasic continuous administration of an active preparation of ethinyl estradiol in an amount of 5 to < 30 pg daily or another synthetic or natural estrogen in an amount equivalent to 5 to < 30 pg ethinyl estradiol daily and a progestin in a contraceptive amount to the female for a first min. period for as long as desired by the female after which the female initiates a break in said administration of said active preparation of 1 to 6 days, and wherein said break is followed by at least one further administration cycle of at least the duration of the first min. period. The contraceptives of the invention can be used to treat other disorders, e.g., PMS and acne.

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L3 ANSWER 2 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN
```

ACCESSION NUMBER: 2004:589241 CAPLUS

DOCUMENT NUMBER: 141:128849

TITLE: Extended transdermal contraceptive regimens INVENTOR(S): Friedman, Andrew Joseph; Laguardia, Katherine D.

PATENT ASSIGNEE(S): USA

SOURCE: U.S. Pat. Appl. Publ., 16 pp., Cont.-in-part of U.S.

Ser. No. 385,597.

CODEN: USXXCO

DOCUMENT TYPE:

Patent

LANGUAGE:

English

FAMILY ACC. NUM. COUNT: 2

PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
US 2004142914	A1	20040722	US 2003-626434	20030724
US 2003219471	A1	20031127	US 2003-385597	20030311
CA 2517778	AA	20040923	CA 2003-2517778	20030724

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WO 2004080442
                              A1
                                      20040923
                                                    WO 2003-US23134
                                                                                20030724
          W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN,
               CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
               LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM,
          ES, EI, LO, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

RW: GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG
                                                                        P 20020311
P 20020517
PRIORITY APPLN. INFO.:
                                                    US 2002-363167P
                                                    US 2002-381585P
                                                    US 2003-385597
                                                                           A2 20030311
                                                    WO 2003-US23134
                                                                            W 20030724
AΒ
     A method of contraception comprises the step of administering to
      a menstruating female a cycle of contraceptive therapy, the cycle of
      therapy including, for at least 42 successive days, the administration of
      a combination of an estrogen and a progestogen in a contraceptively
      effective daily dosage wherein said progestogen is a potent sulfatase
      inhibiting progestogen and said cycle of therapy including 4-8 days which
      are free of estrogen administration following said at least 42 successive
     days. A method of contraception is also described which
     provides enhanced bleeding control and enhanced continuation and
      satisfaction rates in menstruating females using the method. A
     multi-center (10 clin. research sites), open-label study was conducted in
     which 239 regularly menstruating women were randomized 2:1 to receive,
      resp., either norelgestromin/ethinyl estradiol
      (NGM/EE) extended regimen or NGM/EE cyclic regimen for a 112-day treatment
      period. Improved subject compliance with extended transdermal
      administration as compared to cyclic administration of contraceptive
     hormones was observed Significantly longer median time-to-first bleed was
      experienced by subjects receiving extended transdermal administration vs.
      cyclic transdermal administration. Over a 56-day period of continuous
      administration, subjects receiving extended transdermal administration
      experience fewer mean and median bleeding-spotting days as compared to
      subjects receiving cyclic administration.
     ANSWER 3 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN
ACCESSION NUMBER:
                             2003:796529 CAPLUS
DOCUMENT NUMBER:
                             139:286800
TITLE:
                             Pharmaceutical compounds containing estrogens and/or
                             progestins with an aromatase inhibitor and uses for
                             female birth control
INVENTOR(S):
                             Casper, Robert F.
PATENT ASSIGNEE(S):
                             Jencap Research Ltd., Can.
                             PCT Int. Appl., 60 pp.
SOURCE:
```

CODEN: PIXXD2

DOCUMENT TYPE:

Patent

LANGUAGE:

English

FAMILY ACC. NUM. COUNT:

PATENT INFORMATION:

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PATENT NO.
                          KIND
                                    DATE
                                                   APPLICATION NO.
                                                                                   DATE
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                                    _____
                                                   _____
WO 2003082336
                                    20031009 WO 2003-CA493
                           A1
                                                                                  20030403
     W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN,
          CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT,
          TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW
     RW: GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY,
          KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES,
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FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG PRIORITY APPLN. INFO.:

US 2002-369686P P 20020403

AB This invention relates to an improved female birth control method which substantially reduces breakthrough bleeding and mood or emotional disorders in women, and more particularly, to a contraceptive unit comprising at least one aromatase inhibitor combined with a combination of a substance exhibiting estrogen activity, or a substance exhibiting progestin activity, or both substances in amts. required to prevent pregnancy in females.

REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L3 ANSWER 4 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN

ACCESSION NUMBER: 2003:105455 CAPLUS

DOCUMENT NUMBER:

139:1096

TITLE:

Serum distribution of the major metabolites of norgestimate in relation to its pharmacological

properties

AUTHOR(S):

Hammond, Geoffrey L.; Abrams, Larry S.; Creasy, George W.; Natarajan, Jaya; Allen, J. Glyn; Siiteri, Pentti

Κ.

CORPORATE SOURCE:

University of Western Ontario, Department of Obstetrics and Gynecology, London Regional Cancer

Centre, London, ON, N6A 4L6, Can. Contraception (2003), 67(2), 93-99

CODEN: CCPTAY; ISSN: 0010-7824

PUBLISHER:

SOURCE:

Elsevier Science Inc.

DOCUMENT TYPE: LANGUAGE:

Journal English

Norelgestromin (NGMN) and levonorgestrel (LNG) are the main active metabolites of norgestimate (NGM), but their relative contributions to the pharmacol. effects of NGM are unclear. We have therefore determined the serum distribution of these NGM metabolites and assessed their steady-state concns. in women following ≥3 cycles of oral contraceptive (OC) use. The administration of 250 µg NGM/35 µg ethinyl estradiol (EE) resulted in significantly higher sex hormone-binding globulin (SHBG) levels (p = 0.002), and 30% lower serum non-protein-bound (NPB) levels of testosterone, when compared to treatment with 150 µg LNG/30 µg EE. We also confirmed that NGMN does not bind to SHBG, and found that 97.2% of this metabolite is bound to albumin while only 2.8% is in the NPB fraction. In contrast, most of the LNG was bound to SHBG (92.5% and 87.2% after NGM/EE and LNG/EE treatment, resp.), and the NPB fraction of LNG (0.7%) during NGM/EE treatment was lower (p < 0.001) than during LNG/EE treatment (1.4%). Combining these serum distributions with the Cmax and AUCO-24h data obtained after NGM/EE treatment gave NPB and albumin-bound values of NGMN that were much greater than the corresponding LNG values. Furthermore, the Cmax and AUCO-24h values for NPB LNG during NGM/EE treatment were estimated to be lower than during LNG/EE treatment. Since LNG is primarily bound by SHBG, its access to target tissues is restricted. Moreover, because SHBG does not bind NGMN, it appears to be quant. the more important NGM metabolite available to target tissues, and probably accounts for a substantial proportion of the progestogenic activity of NGM/EE OCs. However, it is also possible that simultaneous exposure of NGMN and LNG after treatment with NGM/EE may provide clin. benefits not seen with LNG/EE combinations.

THERE ARE 31 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L3 ANSWER 5 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN

31

ACCESSION NUMBER: 2002:369352 CAPLUS

DOCUMENT NUMBER:

REFERENCE COUNT:

137:114322

TITLE:

The transdermal contraceptive patch: A new approach to

hormonal contraception

AUTHOR(S):

Burkman, Ronald T.

CORPORATE SOURCE:

Department of Obstetrics and Gynecology, Baystate

Medical Center, Springfield, MA, USA

SOURCE:

International Journal of Fertility and Women's

Medicine (2002), 47(2), 69-76

CODEN: IJWMFW

PUBLISHER: DOCUMENT TYPE: Medical Science Publishing International

Journal; General Review

LANGUAGE:

associated

English

A review. The transdermal contraceptive patch delivers ethinyl estradiol and norelgestromin (17-deacetylnorgestimate) at a rate over seven days that results in efficacy paralleling that achieved with oral contraceptives. Due to the pharmacokinetics of the system, adequate steroid levels are maintained for two days beyond the recommended duration of use of an individual patch, with resulting maintenance of efficacy. With perfect use, the failure rate is 0.70 pregnancies per 100 woman-years and for typical use, the rate is 0.88 pregnancies per 100 woman-years. Body weight above 90 kg (198 lb) is

with lower efficacy. Cycle control is similar to that achieved by oral contraceptives. With the exception of a transient increase in breast tenderness, the side effect profile is similar to that noted by oral contraceptive users. A major advantage of this method compared to oral contraceptives is a nearly 90% perfect adherence to the dosing schedule across all age groups. Partial or total detachment of the patch occurs at an overall rate of 3.8%. This rate is not affected by warm humid climates, vigorous exercise, or exposure to saunas or water baths. 22

REFERENCE COUNT:

THERE ARE 22 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

ANSWER 6 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN

ACCESSION NUMBER:

.2002:128838 CAPLUS

DOCUMENT NUMBER:

136:257419

TITLE:

Transdermal contraception: Evaluation of

three transdermal norelgestromin/ ethinyl estradiol doses in a

randomized, multicenter, dose-response study

Dittrich, Richard; Parker, Lamar; Rosen, Jeffrey B.; Shangold, Gary; Creasy, George W.; Fisher, Alan C.

CORPORATE SOURCE:

Ortho Evra/Evra 001 Study Group, Partners in Women's Health, Methodist Hospital, Philadelphia, PA, USA American Journal of Obstetrics and Gynecology (2002),

SOURCE:

AUTHOR(S):

186(1), 15-20 CODEN: AJOGAH; ISSN: 0002-9378

PUBLISHER: Mosby, Inc. DOCUMENT TYPE: Journal LANGUAGE: English

The objective of this study was to identify the dose for a contraceptive patch that provides a predetd. level of ovulation suppression and cycle control and that is well tolerated. In this randomized study, 610 subjects received 10-, 15-, or 20-Cm2 patch dose sizes (20-Cm2, Ortho Evra/Evra) (Janssen Pharmaceutica, NV Belgium) or Ortho-Cyclen/Cilest (Janssen Pharmaceutica, NV Belgium) for up to 4 cycles. As with Ortho-Cyclen, patch regimens included 21 dosing days (3 consecutive 7-day patches) followed by 1 dose-free week. The patch regimens demonstrated a dose-response for ovulation suppression and cycle control. Presumed ovulation, determined on the basis of serum progesterone concns. ≥ 3 ng/mL in cycles 1 and 3, occurred in 6.2% (Ortho Evra) and 7.2% (Ortho-Cyclen) of subjects. At cycle 3, breakthrough bleeding/spotting was reported by 10.5% and 15.0% of subjects, resp. Compliance with each patch was superior to that with Ortho-Cyclen. All regimens had safety profiles typical of oral contraceptives. The 20-Cm2 patch (Ortho Evra) provided ovulation suppression, cycle control, and safety similar to that of Ortho-Cyclen, with significantly better compliance.

REFERENCE COUNT: 13 THERE ARE 13 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L3 ANSWER 7 OF 36 CAPLUS COPYRIGHT 2006 ACS on STN

ACCESSION NUMBER: 2001:623888 CAPLUS

DOCUMENT NUMBER: 135:339363

TITLE: Norgestimate: From the laboratory to three clinical

indications

AUTHOR(S): Henzl, Milan R.

CORPORATE SOURCE: Department of Obstetrics and Gynecology, Stanford

University School of Medicine, Stanford, CA, USA Journal of Reproductive Medicine (2001), 46(7),

647-661

CODEN: JRPMAP; ISSN: 0024-7758

PUBLISHER: Journal of Reproductive Medicine, Inc.

DOCUMENT TYPE: Journal; General Review

LANGUAGE: English

SOURCE:

A review with refs. This review of preclin. studies and clin. trials of efficacy and safety examines the relation between structure and function in the norgestimate (NGM) mol., describes the pharmacol. characteristics of NGM and evaluates clin. experience with NGM in oral contraception (OC), treatment of hyperandrogenism in women and hormonal replacement therapy (HRT). NGM is a progestin of the 19-norsteroid series with an oxime group on C-3. In women, only low serum levels of NGM can be detected for five hours after ingestion. NGM is swiftly converted into its main metabolite, the 17-deacetylated norgestimat (norelgestromin), which carries the progestogenic properties of NGM. The metabolite reaches a mean peak concentration of 3,500 pg/mL 1.5 h after intake and has a half-life of > 24 h. The progestogenic potency of NGM and its main metabolite is comparable to that of progesterone. The doses of NGM in OCs effectively inhibit ovulation and control uterine bleeding. In the triphasic NGM/ethinyl estradiol (EE) OC, the total monthly load of progestin is only 4.5 mg. NGM has a low androgenic impact and does not interfere with the pos. metabolic actions of estrogens, notably the estrogen-induced increase in high-d. lipoprotein levels. OCs with NGM and EE increase the serum concentration

of sex hormone binding globulin threefold, augmenting the binding of circulating testosterone and reducing free testosterone levels by 50%. Consequently, OCs with NGM are therapeutic for hyperandrogenic symptoms, such as acne. In a new type of HRT three-day dosing with $17\beta\mbox{-estradiol}$ (E2) alone is followed by three-day dosing with E2 plus NGM. This regimen treats vasomotor symptoms, protects the endometrium from hyperproliferation and is associated with a favorable lipid profile. NGM is a versatile progestin suitable for medical use from adolescence through the reproductive years to menopause.

REFERENCE COUNT: 48 THERE ARE 48 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L3 ANSWER 8 OF 36 MEDLINE on STN ACCESSION NUMBER: 2005317984 MEDLINE DOCUMENT NUMBER: PubMed ID: 15966567

TITLE: Transdermal ethinylestradiol/norelgestromin: a

review of its use in hormonal contraception.

AUTHOR: Goa Karen L; Warner Gregory T; Easthope Stephanie E

CORPORATE SOURCE: Adis International Inc., Langhorne, Pennsylvania 19047,

USA.

SOURCE: Treat Endocrinol, (2003) 2 (3) 191-206. Ref: 37

Journal code: 101132977. ISSN: 1175-6349.

PUB. COUNTRY: New Zealand

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

General Review; (REVIEW)

. LANGUAGE: English

FILE SEGMENT: Priority Journals

ENTRY MONTH:

200507

ENTRY DATE:

Entered STN: 20050622

Last Updated on STN: 20050716 Entered Medline: 20050715

AB Ethinylestradiol 20 microg/day plus norelgestromin 150 microg/day have been formulated into a transdermal patch for hormonal contraception. The predominant mechanism of action for transdermal ethinylestradiol/norelgestromin (Ortho Evra, Evra) is inhibition of ovulation by suppression of gonadotropins. It suppresses follicular development, induces changes to the endometrium that reduce the probability of implantation, and increases the viscosity of cervical mucus, which may prevent sperm penetration into the uterus. Two large randomized, nonblind efficacy studies demonstrated that transdermal ethinylestradiol/norelgestromin was as efficacious in preventing pregnancy as oral triphasic ethinylestradiol/levonorgestrel or oral ethinylestradiol/desogestrel. A large, noncomparative study also showed transdermal ethinylestradiol/norelgestromin to have good contraceptive efficacy. Moreover, in the two comparative trials, women using transdermal ethinylestradiol/norelgestromin had higher rates of perfect compliance than women using oral contraception. Age did not affect the rate of perfect compliance in women using the transdermal ethinylestradiol/norelgestromin patch, whereas the rate of compliance reduced with younger age in oral contraceptive users. Pooled results from three efficacy studies found that 1.8% of patches were replaced as a result of complete detachment and 2.9% because of partial detachment. Physical exercise, water immersion, and living in a humid climate did not affect patch adhesion. Transdermal ethinylestradiol/ norelgestromin was generally well tolerated in clinical trials. The most common menstrual disturbances were breakthrough bleeding/spotting and dysmenorrhea. The incidence of discontinuation of treatment because of an adverse event was < or = 3.2%, with the most common reason being application-site reactions. CONCLUSIONS: Transdermal ethinylestradiol/ norelgestromin offers a well tolerated, effective, reversible, and easy-to-use method of hormonal contraception with an increased likelihood of compliance relative to oral contraceptives.

L3 ANSWER 9 OF 36 MEDLINE on STN ACCESSION NUMBER: 2005303284 MEDLINE DOCUMENT NUMBER: PubMed ID: 15950671

TITLE:

AUTHOR:

SOURCE:

Suppression of estrogen-withdrawal headache with extended

transdermal contraception.

LaGuardia Katherine D; Fisher Alan C; Bainbridge James D;

LoCoco John M; Friedman Andrew J

CORPORATE SOURCE:

Clinical Affairs, Ortho-McNeil Pharmaceutical, Inc.,

Raritan, New Jersey 08869, USA.. klaguard@ompus.jnj.com Fertility and sterility, (2005 Jun) 83 (6) 1875-7.

Journal code: 0372772. ISSN: 1556-5653.

United States

PUB. COUNTRY: DOCUMENT TYPE:

Journal; Article; (JOURNAL ARTICLE)

(MULTICENTER STUDY)

(RANDOMIZED CONTROLLED TRIAL)

(CLINICAL TRIAL)

LANGUAGE:

English

FILE SEGMENT:

Priority Journals

ENTRY MONTH:

200601

ENTRY DATE:

Entered STN: 20050614

Last Updated on STN: 20060104 Entered Medline: 20060103

AB A randomized clinical trial was conducted with 239 women at nine clinical research sites to compare bleeding profile, headache frequency, and subject satisfaction with the transdermal contraceptive, ORTHO EVRA (norelgestromin/ethinyl estradiol transdermal system) used in an extended regimen (84 days) with a traditional, 28-day cyclic regimen. In a majority of women studied, compared with cyclic use,

extended use of transdermal norelgestromin/ethinyl estradiol delayed menses and reduced the total incidence of mean headache days during the hormone-free interval.

L3 ANSWER 10 OF 36 MEDLINE on STN ACCESSION NUMBER: 2005291286 MEDLINE

DOCUMENT NUMBER: PubMed ID: 15937609

TITLE: Preference for and satisfaction of Canadian women with the

transdermal contraceptive patch versus previous

author: contraceptive method: an open-label, multicentre study.

Weisberg Fay; Bouchard Celine; Moreau Michele; Audet Marie

Claude; Mawdsley Scott; Dattani Dan; Dinniwell Julie;

Horbay G L A

CORPORATE SOURCE: Department of Obstetrics and Gynaecology, University of

Toronto, Toronto ON. (NRGEEP-CON-401 Study Group).

SOURCE: Journal of obstetrics and gynaecology Canada: JOGC =

Journal d'obstetrique et gynecologie du Canada : JOGC,

(2005 Apr) 27 (4) 350-9.

Journal code: 101126664. ISSN: 1701-2163.

PUB. COUNTRY: Canada

DOCUMENT TYPE: (CLINICAL TRIAL)

(CLINICAL TRIAL, PHASE IV)

Journal; Article; (JOURNAL ARTICLE)

(MULTICENTER STUDY)

LANGUAGE: English

FILE SEGMENT: Priority Journals

ENTRY MONTH: 200509

ENTRY DATE: Entered STN: 20050607

Last Updated on STN: 20050914 Entered Medline: 20050913

AB OBJECTIVE: To document Canadian women's experience with the transdermal contraceptive patch, a method delivering 150 microg norelgestromin and 20 microg ethinyl estradiol daily. METHODS: We conducted an open-label, multicentre, descriptive cohort study of the contraceptive patch over 9 cycles in 392 women requiring contraception. A single treatment cycle consisted of 3 consecutive 7-day patch applications followed by 1 patch-free week. At the final visit, overall satisfaction and preference for the patch was rated and compared with the previously used contraceptive method. RESULTS: At baseline, 80.9% of participants were either very satisfied or somewhat satisfied with their previous contraceptive method, 89% having used oral contraceptives. At final observation, 60.6% of participants preferred the patch, 9.3% had no preference; and 30% preferred their previous method (n = 376). A total of 279 participants (71.2%) completed 9 cycles of patch use. Of these, 91% were satisfied with the patch and 74.9% preferred the patch to their previous contraceptive (43% strongly preferred and 31.9% preferred); 9% had no preference; and 16.1% preferred their previous method. Of those who preferred the patch, 82.7% preferred it because of its convenience or simplicity. Across all cycles, 88% of participants recorded perfect compliance. The most common adverse event was application site reactions (most of which were mild), experienced by 49% of participants: 33.7%, 16.5%, and 14.7% at cycles 1, 4, and 9, respectively. CONCLUSION: Both preference for and satisfaction with the transdermal contraceptive patch were high. Most participants.

=> d ibib abs 13 11-36

L3 ANSWER 11 OF 36 MEDLINE on STN
ACCESSION NUMBER: 2004613434 MEDLINE
DOCUMENT NUMBER: PubMed ID: 15586908
TITLE: New contraception options.

AUTHOR: Smith Monica J

SOURCE: Diabetes self-management, (2004 Sep-Oct) 21 (5) 20-2, 25.

Journal code: 9883682. ISSN: 0741-6253.

PUB. COUNTRY: United States

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

LANGUAGE: English

FILE SEGMENT: Consumer Health ·

ENTRY MONTH: 200412

ENTRY DATE: Entered STN: 20041220

Last Updated on STN: 20041220 Entered Medline: 20041213

L3 ANSWER 12 OF 36 MEDLINE on STN ACCESSION NUMBER: 2004560184 MEDLINE DOCUMENT NUMBER: PubMed ID: 15532134

TITLE: Ethinylestradiol + norelgestromin: new

preparation. Transdermal contraception: no

tangible progress.

AUTHOR: Anonymous

SOURCE: Prescrire international, (2004 Aug) 13 (72) 123-6.

Journal code: 9439295. ISSN: 1167-7422.

PUB. COUNTRY: France

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

LANGUAGE: English

FILE SEGMENT: Health Technology

ENTRY MONTH: 200411

ENTRY DATE: Entered STN: 20041110

Last Updated on STN: 20041220 Entered Medline: 20041124

AB (1) The reference hormone-based contraceptive for women is an oral contraceptive combining ethinylestradiol (about 30 micrograms) and a well-known progestin such as levonorgestrel or norethisterone. (2) A transdermal contraceptive patch delivering 20 micrograms of ethinylestradiol and 150 micrograms of norelgestromin over 24 hours, and designed to be left in place for a whole week, three weeks a month, has recently been marketed in France. (3) Norelgestromin is the active metabolite of norgestimate, which is already available in combined contraceptives but is less well evaluated than some other progestins. Norelgestromin is metabolised by the liver, notably into norgestrel. (4) The clinical evaluation dossier of the new transdermal contraceptive contains data from two comparative unblinded trials, one versus a triphasic combination of oral ethinylestradiol + levonorgestrel, and the other versus oral ethinyl estradiol (20 micrograms) + desogestrel. A third, non comparative trial offers weaker evidence. These three trials included about 3300 women in total, and lasted between 6 and 13 cycles. The patch was about as effective as the comparator contraceptives. (5) In the three main clinical trials, 4.7% of patches had to be replaced because they became unstuck, either completely (1.8%) or partially (2.9%). (6) More women dropped out of the groups using patches (19.9% of the patch group compared with 14.5% of the group taking oral contraceptives in one trial, 29.6% versus 24.3% in the other trial). Women using the patch were more likely than other women to stop their treatment because of adverse events (about 12% versus 5%). (7) Breast discomfort, breast tenderness or pain were reported by 22% of women using the patches and by 9% and 6% of women in the two comparator groups. Women using the patches had slightly longer menstrual periods (5.6 days versus 4.7 days). Reactions at the patch site were reported by 17% of women. (8) There is no evidence that the patch is any less likely than reference oral contraceptives to cause thromboembolism. The true thromboembolic risk associated with the new patches is unknown. (9) Used patches still contain large amounts of active substances, and must be placed in sachets (provided in the packet) and taken to a pharmacy for disposal. (10) In practice, the reference combined contraceptive for women is still oral ethinylestradiol (about 30 micrograms) plus a well-known progestin such as levonorgestrel or norethisterone. Ethinylestradiol + norelgestromin patches offer

women no real benefits: they are probably less convenient and may be less safe.

ANSWER 13 OF 36 MEDLINE on STN ACCESSION NUMBER: 2004418089 MEDLINE DOCUMENT NUMBER: PubMed ID: 15323313

TITLE: [Transdermal contraception -- a new beginning].

Transdermalnata kontratseptsiia--edno novo nachalo.

AUTHOR: Sigridov I; Dikov I; Ivanov S

Akusherstvo i ginekologiia, (2004) 43 Suppl 1 19-27. Ref: SOURCE:

Journal code: 0370455. ISSN: 0324-0959.

PUB. COUNTRY: Bulgaria

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

General Review; (REVIEW)

(REVIEW, TUTORIAL)

LANGUAGE: Bulgarian

FILE SEGMENT: Priority Journals

ENTRY MONTH: 200412

Entered STN: 20040825 ENTRY DATE:

Last Updated on STN: 20041220 Entered Medline: 20041214

ANSWER 14 OF 36 MEDLINE on STN 2004117856 ACCESSION NUMBER: MEDLINE DOCUMENT NUMBER: PubMed ID: 15006313

TITLE:

New Product Review (September 2003). Norelgestromin /ethinyl oestradiol transdermal contraceptive system

(Evra).

AUTHOR: Anonymous

CORPORATE SOURCE: Clinical Effectiveness Unit, Faculty of Family Planning and

Reproductive Health Care, Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, Regent's Park, London NW1 4RG, UK. (Faculty of Family Planning and Reproductive

Health Care Clinical Effectiveness Unit).

ffp.ceu@abdn.ac.uk

SOURCE: journal of family planning and reproductive health care /

Faculty of Family Planning & Reproductive Health Care, Royal College of Obstetricians & Gynaecologists, (2004 Jan)

30 (1) 43-5.

Journal code: 101087687. ISSN: 1471-1893.

PUB. COUNTRY: England: United Kingdom

DOCUMENT TYPE: (GUIDELINE)

Journal; Article; (JOURNAL ARTICLE)

(PRACTICE GUIDELINE)

LANGUAGE: English

FILE SEGMENT: Priority Journals

ENTRY MONTH: 200403

Entered STN: 20040311 ENTRY DATE:

Last Updated on STN: 20040401 Entered Medline: 20040331

AΒ This new transdermal contraceptive system (contraceptive patch), Evra (Janssen-Cilag), received a UK product licence in 2003. In clinical trials: Consistent doses of norelgestromin and ethinyl oestradiol are released into the systemic circulation daily. Pharmacokinetic data suggest that levels are sufficient to inhibit ovulation for at least 7 days. The overall Pearl index for the contraceptive patch (1.24; 95% CI 0.19-2.33) was similar to that of a triphasic combined oral contraceptive (COC) pill (2.18; 95% CI 0.57-3.8). Self-reported "perfect" compliance was significantly better with the contraceptive patch (88.2%) than with a combined contraceptive pill (77.7%). Patch detachment, requiring replacement with a new patch, with normal daily activity is uncommon (4.6%). Breakthrough bleeding and

spotting were significantly more common with the contraceptive patch than

with combined oral contraception in the first two cycles but differences were not significant by cycle three. In general, reported side effects were not significantly different with contraceptive patch or combined pill use. However, breast tenderness in the first two treatment cycles was more common with patch use. Symptoms were mild to moderate in 85% of women and were rarely treatment limiting. Currently, there are limited data regarding risk of venous thromboembolism, and cervical or breast cancer with the contraceptive patch. No clinically significant alterations in metabolic or haemostatic parameters were identified with contraceptive patch use. A month's supply of the contraceptive patch costs 7.74 UK pounds. Combined oral contraception prices range from approximately 0.80 to 5.00 UK pounds and hormone replacement therapy patches range from 10.00 to 13.00 UK pounds. The contraceptive patch offers additional choice for women who wish to use a combined hormonal method of contraception.

L3 ANSWER 15 OF 36 MEDLINE on STN ACCESSION NUMBER: 2004024643 MEDLINE DOCUMENT NUMBER: PubMed ID: 14723093

TITLE: Evra--a patch on oral contraception?.

AUTHOR: Anonymous

SOURCE: Drug and therapeutics bulletin, (2003 Dec) 41 (12) 89-91.

Ref: 12

Journal code: 0112037. ISSN: 0012-6543.

PUB. COUNTRY: England: United Kingdom

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

General Review; (REVIEW)

LANGUAGE: English

FILE SEGMENT: Priority Journals

ENTRY MONTH: 200402

ENTRY DATE: Entered STN: 20040116

Last Updated on STN: 20040212 Entered Medline: 20040211

AB Evra (Janssen-Cilag) is the first contraceptive to be available as a skin patch. In promotional material aimed at healthcare professionals, the company claims that Evra offers a "once-weekly method of contraception" with "more than 99% effectiveness and excellent compliance". The company's website for women using Evra carries the slogan "Evra The Right Contraceptive Choice" and claims that the patch is "just as effective as the contraceptive pill". Each patch is intended to be worn for 7 days, in contrast to combined oral contraceptives (COCs), which need to be taken daily. Here we assess whether Evra offers real advantages over COCs and consider its place as a contraceptive option.

L3 ANSWER 16 OF 36 MEDLINE ON STN ACCESSION NUMBER: 2003436193 MEDLINE DOCUMENT NUMBER: PubMed ID: 13677551

TITLE: Progress in contraception: new technology.

AUTHOR: Linn Edward S

CORPORATE SOURCE: Department of Ob/Gyn, Lutheran General Hospital, Park

Ridge, Illinois 60068-1174, USA.

SOURCE: International journal of fertility and women's medicine,

(2003 Jul-Aug) 48 (4) 182-91. Ref: 47

Journal code: 9706778. ISSN: 1534-892X.

PUB. COUNTRY: United States

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

General Review; (REVIEW)

(REVIEW, TUTORIAL)

LANGUAGE: English

FILE SEGMENT: Priority Journals

ENTRY MONTH: 200402

ENTRY DATE: Entered STN: 20030919

Last Updated on STN: 20040206 Entered Medline: 20040205

Unintended pregnancy continues to be a major public health issue in this AB country. Approximately 50% of pregnancies in the United States are unintended, and, of these, half end in abortion. Although tubal sterilization is highly effective, many women subsequently express regret and remorse. Oral contraceptives represent an effective, reversible method. However, many women have difficulty using them consistently and correctly. Recently, four new delivery systems for hormonal contraception have become available in the United States: the monthly injection, the levonorgestrel intrauterine system, the combination hormonal contraceptive vaginal ring, and the transdermal contraceptive patch. All four new methods are effective, readily reversible, generally discreet, and reduce daily compliance challenges. The monthly injection, vaginal ring, and transdermal patch can be discontinued without the need for an office visit. This expanded menu of effective contraceptive options should help women find a method that suits their particular life style.

ANSWER 17 OF 36 MEDLINE on STN ACCESSION NUMBER: 2003414530 MEDLINE DOCUMENT NUMBER:

PubMed ID: 12953327

TITLE:

Transdermal delivery of sex steroids for hormone replacement therapy and contraception. A review

of principles and practice. Henzl Milan R; Loomba Preeti K

AUTHOR: CORPORATE SOURCE:

Department of Gynecology and Obstetrics, Stanford

University School of Medicine, Stanford, California, USA..

mhenzl@aol.com

SOURCE:

Journal of reproductive medicine, (2003 Jul) 48 (7) 525-40.

Ref: 65

Journal code: 0173343. ISSN: 0024-7758.

PUB. COUNTRY:

United States

DOCUMENT TYPE:

Journal; Article; (JOURNAL ARTICLE)

General Review; (REVIEW)

(REVIEW, TUTORIAL)

LANGUAGE:

English

FILE SEGMENT:

Priority Journals

ENTRY MONTH:

200311

ENTRY DATE:

Entered STN: 20030905

Last Updated on STN: 20031218 Entered Medline: 20031126

AR The percutaneous route is an effective method for delivery of reproductive hormones. Several transdermal therapeutic systems (TTS) releasing estrogens, progestogens and androgens from patches attached to the skin are currently in clinical use. For women, transdermal systems have been developed for hormonal replacement therapy (HRT) and recently for contraception. HRT with patches releasing only estradiol (E2) should be supplemented with a progestogen to protect the endometrium. Patches simultaneously releasing both E2 and a progestogen are also available. Combined regimens are either continuous or sequential. In the latter, estrogen-only patches are applied for 14 days, followed by 14-day application of patches releasing both hormones. Transdermal HRT successfully treats menopausal symptoms and has a bone-sparing effect. Transdermal contraceptive patches deliver ethinyl E2 in combination with the progestogen norelgestromin. This system provides an effective contraceptive and acceptable bleeding pattern not different from that of oral contraceptives. The types of adverse events experienced are approximately the same as with oral contraceptives. Reactions at the application site cause about 3% women to discontinue the use of patches. Transdermal systems also have been designed to supplement testosterone in hypogonadal men. Testosterone released from patches produces positive effects on mood and sexual behavior and significantly increases bone mass. Men using testosterone patches have to be regularly monitored for an increase in prostate volume and changes in prostate-specific antigen. Reproductive steroids delivered by the skin avoid first-pass liver

metabolism, typical of oral dosing; consequently, the liver tissue is affected to a lesser degree. Other advantages include rapid onset and termination of action, noninvasive self-administration and attainment of therapeutic hormone levels with low daily doses. Reduced frequency of dosing has the potential to improve patient compliance. While compliance is important for any hormone, it is particularly important for contraceptive purposes. Like oral delivery of sex steroids, percutaneous absorption is characterized by intra- and interindividual variability. New technologies under development, combining electronics and low-frequency ultrasound, have the potential to provide precise dosing as well as drug delivery "on demand."

ANSWER 18 OF 36 MEDLINE on STN ACCESSION NUMBER: 2002069992 MEDLINE DOCUMENT NUMBER: PubMed ID: 11727179

TITLE:

Transdermal contraception.

AUTHOR:

Creasy G W; Abrams L S; Fisher A C

CORPORATE SOURCE:

The R.W. Johnson Pharmaceutical Research Institute,

Raritan, New Jersey 08869, USA.

SOURCE:

Seminars in reproductive medicine, (2001 Dec) 19 (4)

373-80. Ref: 30

Journal code: 100909394. ISSN: 1526-8004.

PUB. COUNTRY:

United States

DOCUMENT TYPE:

Journal; Article; (JOURNAL ARTICLE)

General Review; (REVIEW)

(REVIEW, TUTORIAL)

LANGUAGE:

English

FILE SEGMENT:

Priority Journals

ENTRY MONTH:

200203

ENTRY DATE:

Entered STN: 20020125

Last Updated on STN: 20020320 Entered Medline: 20020319

AB This review summarizes the clinical studies involving the once-weekly Ortho Evra/Evra contraceptive patch. The patch delivers norelgestromin (NGMN), 150 microg, and ethinyl estradiol (EE), 20 microg, daily to the systemic circulation. contraceptive patch provided ovulation suppression and cycle control similar to that of oral norgestimate 250 microg/EE 35 microg, significantly decreased mean maximum follicular diameter following a 3-day intentional delayed dosing phase when compared with oral levonorgestrel (LNG) 50/75/125 microg/EE 30/40/30 micorg and oral LNG 100 microg/EE 20microg, and was as effective as oral LNG 50/75/125 microg/EE 30/40/30 microg and oral desogestrel 150 microg/EE 20 microg in altering cervical mucus composition (i.e., creating a scanty, viscous consistency). contraceptive patch provided efficacy, cycle control, and safety comparable to that seen with oral LNG 50/75/125 microg/EE 30/40/30 microg, but women were able to correctly follow the weekly dosing regimen significantly more often than the daily oral contraceptive dosing regimen. Less than 2% of patches were replaced because of complete detachment in these trials. The patch was not associated with phototoxicity or photoallergy. The contraceptive patch, the only noninvasive, weekly birth control method that a woman can self-administer, will be a valuable addition to current contraceptive options.

ANSWER 19 OF 36 MEDLINE on STN ACCESSION NUMBER: 2001653975 MEDLINE DOCUMENT NUMBER: PubMed ID: 11704172

TITLE: Efficacy and safety of a transdermal contraceptive system.

Smallwood G H; Meador M L; Lenihan J P; Shangold G A;

Fisher A C; Creasy G W

CORPORATE SOURCE:

R.W. Johnson Phamaceutical Research Institute, Raritan, NJ, AGI.025

USA. (ORTHO EVRA/EVRA 002 Study Group).

SOURCE:

AUTHOR:

Obstetrics and gynecology, (2001 Nov) 98 (5 Pt 1) 799-805.

Journal code: 0401101. ISSN: 0029-7844.

PUB. COUNTRY: United States
DOCUMENT TYPE: (CLINICAL TRIAL)

Journal; Article; (JOURNAL ARTICLE)

(MULTICENTER STUDY)

LANGUAGE: English

FILE SEGMENT: Abridged Index Medicus Journals; Priority Journals

ENTRY MONTH: 200112

ENTRY DATE: Entered STN: 20011115

Last Updated on STN: 20020123 Entered Medline: 20011205

AB OBJECTIVES: To evaluate the efficacy, cycle control, compliance, and safety of a transdermal contraceptive system that delivers norelgestromin 150 microg and ethinyl estradiol

20 microg daily. METHODS: In this open-label, 73-center study, 1672 healthy, ovulatory, sexually active women received ORTHO EVRA/EVRA for six (n = 1171) or 13 cycles (n = 501). The treatment regimen for each cycle was three consecutive 7-day patches (21 days) followed by 1 patch-free week. RESULTS: The overall and method-failure probabilities of pregnancy through 13 cycles were 0.7% and 0.4%, respectively. The incidence of breakthrough bleeding was low throughout the study. Perfect compliance (21 consecutive days of dosing, followed by a 7-day drug-free interval; no patch could be worn for more than 7 days) was achieved in 90% of subject cycles; only 1.9% of patches detached completely. Adverse events were typical of hormonal contraception, and most were mild-to-moderate in severity and not treatment limiting. The most common adverse events resulting in discontinuation were application site.

mild-to-moderate in severity and not treatment limiting. The most commadverse events resulting in discontinuation were application site reactions (1.9%), nausea (1.8%), emotional lability (1.5%), headache (1.1%), and breast discomfort (1.0%). CONCLUSIONS: The transdermal contraceptive patch provides effective contraception and cycle control, and is well tolerated. The weekly change schedule for the contraceptive patch is associated with excellent compliance and wearability characteristics.

L3 ANSWER 20 OF 36 BIOSIS COPYRIGHT (c) 2006 The Thomson Corporation on STN

ACCESSION NUMBER: 2005:30740 BIOSIS DOCUMENT NUMBER: PREV200500031158

TITLE: Hormonal contraception: recent advances and

controversies.

AUTHOR(S): Practice Comm Amer Soc Reprod Med [Reprint Author]
SOURCE: Fertility and Sterility, (September 2004) Vol. 82, No.

Suppl. 1, pp. S26-S32. print. ISSN: 0015-0282 (ISSN print).

DOCUMENT TYPE: Article

General Review; (Literature Review)

LANGUAGE: English

ENTRY DATE: Entered STN: 12 Jan 2005

Last Updated on STN: 12 Jan 2005

AB This document will outline new delivery systems and contraceptive formulations, summarize recent advances in emergency contraception, and review the effects of hormonal contraception on cancer

risks, cardiovascular disease, and bone. (Fertil Steril(R) 2004;82(Suppl 1):26-32. Copyright 2004 by American Society for Reproductive Medicine.).

L3 ANSWER 21 OF 36 EMBASE COPYRIGHT (c) 2006 Elsevier B.V. All rights reserved on STN

ACCESSION NUMBER: 2005187751 EMBASE

TITLE: Ethinyl estradiol/levonorgestrel

(seasonale) for oral contraception.

AUTHOR: Wilson S.A.; Kudis H.A.

CORPORATE SOURCE: Dr. S.A. Wilson, Univ. of Pittsburgh Medical Center, St.

Margaret Fam. Residency Program, Pittsburgh, PA, United

States

SOURCE: American Family Physician, (15 Apr 2005) Vol. 71, No. 8,

pp. 1581-1582.

Refs: 3

ISSN: 0002-838X CODEN: AFPYAE

COUNTRY: United States

DOCUMENT TYPE: Journal; (Short Survey)

FILE SEGMENT: 010 Obstetrics and Gynecology

> 036 Health Policy, Economics and Management

037 Drug Literature Index 038 Adverse Reactions Titles

LANGUAGE: English English SUMMARY LANGUAGE:

ENTRY DATE: Entered STN: 20050602

Last Updated on STN: 20050602

Ethinyl estradiol/levonorgestrel (Seasonale) is the AB first extended-cycle oral contraceptive. With Seasonale, women take active hormone for 84 consecutive days, then hormone-free tablets for 7 days, resulting in one menstrual period every three months. Each active tablet contains 30 mcg of ethinyl estradiol and 150 mcg of levonorgestrel.

ANSWER 22 OF 36 EMBASE COPYRIGHT (c) 2006 Elsevier B.V. All rights L3 reserved on STN

ACCESSION NUMBER: 2005165151 EMBASE

Effect of multiple-dose dexloxiglumide on the TITLE:

pharmacokinetics of oral contraceptives in healthy women. AUTHOR: Roy P.; Jakate A.S.; Patel A.; Abramowitz W.; Wangsa J.;

Persiani S.; Kapil R.

CORPORATE SOURCE: Dr. R. Kapil, Forest Research Institute, Harborside

Financial Center, Plaza V, Jersey City, NJ 07311, United

States

SOURCE: Journal of Clinical Pharmacology, (2005) Vol. 45, No. 3,

pp. 329-336. Refs: 20

ISSN: 0091-2700 CODEN: JCPCBR

COUNTRY: United States DOCUMENT TYPE: Journal; Article

FILE SEGMENT: 010 Obstetrics and Gynecology

> 030 Pharmacology

037 Drug Literature Index 038 Adverse Reactions Titles

048 Gastroenterology

LANGUAGE: English SUMMARY LANGUAGE: English

ENTRY DATE: Entered STN: 20050505

Last Updated on STN: 20050505

This study was undertaken to evaluate the effect of dexloxiglumide, a selective cholecystokinin receptor antagonist, on the pharmacokinetics of a combination oral contraceptive (OC). A single-blind, placebo-controlled, 2-period crossover study was conducted in 24 healthy young female subjects who received Ortho Tri-Cyclen containing ethinyl estradiol (EE, 0.035 mg) and norgestimate (NE, 0.180 mg/0.215 mg/0.250 mg per 7-day phase, respectively) for 5 days (days 17-21) concurrently with either 200 mg dexloxiglumide (3 times a day on days 17-20, followed by a single dose on day 21) or matching placebo during 2 consecutive 28-day OC dosing cycles. Plasma was sampled up to 24 hours for the determination of EE, NE, and 17-deactyl norgestimate (17-DNE, a rapidly formed pharmacologically active metabolite of NE). geometric mean ratios (GMRs, dexloxiglumide/placebo) of the plasma concentration-time curve over 24 hours with corresponding 90% confidence intervals (CIs) for EE and 17-DNE were 1.21 (1.17-1.26) and 0.92 (0.89-0.95), respectively. The GMRs (90% CI) of C (max) for EE and 17-DNEwere 1.15 (1.09-1.20) and 0.93 (0.90-0.96), respectively. Coadministration of OC and dexloxiglumide was well tolerated and safe. Comparable systemic exposure of EE and 17-DNE in the presence and absence

of dexloxiglumide suggests that dexloxiglumide treatment is unlikely to interfere with the safety and efficacy of oral contraceptives based on the analysis of the resulting pharmacokinetic profile. .COPYRGT.2005 the American College of Clinical Pharmacology.

L3 ANSWER 23 OF 36 EMBASE COPYRIGHT (c) 2006 Elsevier B.V. All rights reserved on STN

ACCESSION NUMBER: 2004193633 EMBASE

TITLE: The transdermal contraceptive system.

AUTHOR: Burkman R.T.

CORPORATE SOURCE: Dr. R.T. Burkman, Department of Obstetrics/Gynecology,

Baystate Medical Center, 759 Chestnut St, Springfield, MA

01199, United States. rtb@bhs.org

SOURCE: American Journal of Obstetrics and Gynecology, (2004) Vol.

190, No. 4 SUPPL., pp. S49-S53.

Refs: 12

ISSN: 0002-9378 CODEN: AJOGAH

COUNTRY: United States

DOCUMENT TYPE: Journal; General Review

FILE SEGMENT: 010 Obstetrics and Gynecology

O37 Drug Literature Index O38 Adverse Reactions Titles

039 Pharmacy

LANGUAGE: English SUMMARY LANGUAGE: English

ENTRY DATE: Entered STN: 20040610

Last Updated on STN: 20040610

AB The transdermal contraceptive system or contraceptive patch (Ortho EVRA, Ortho-McNeil Pharmaceuticals, Raritan, NJ), approved by the Food and Drug Administration in November 2001, is a novel combination hormonal contraceptive that contains the hormones norelgestromin and ethinyl estradiol. In clinical trials, the contraceptive patch was shown to have comparable safety and efficacy with that of oral contraceptives (OCs), and results indicated that the women who used the patch did so more correctly and consistently than those who used OCs. The enhanced patient compliance may be due to the once-a-week dosing and relative ease of use of this system. The transdermal delivery approach minimizes the "peaks and troughs" of hormone concentrations associated with daily oral administration and avoids hepatic first-pass metabolism. Side effects are similar to those seen with OCs with the exception of application site reactions that are obviously unique to transdermal delivery. .COPYRGT. 2004 Elsevier Inc. All rights reserved.

L3 ANSWER 24 OF 36 EMBASE COPYRIGHT (c) 2006 Elsevier B.V. All rights reserved on STN

ACCESSION NUMBER: 2004171589 EMBASE

TITLE: Oral contraception over the age of 40.

AUTHOR: Kovacs L.

CORPORATE SOURCE: Dr. L. Kovacs, Semmelweis u. 1, H-6725 Szeged, Hungary.

kovacs@obgyn.szote.u-szeged.hu

SOURCE: Annals of the New York Academy of Sciences, (2003) Vol.

997, pp. 194-198.

Refs: 14

ISSN: 0077-8923 CODEN: ANYAA

COUNTRY: United States

DOCUMENT TYPE: Journal; Conference Article

FILE SEGMENT: 010 Obstetrics and Gynecology

037 Drug Literature Index 038 Adverse Reactions Titles

LANGUAGE: English SUMMARY LANGUAGE: English

ENTRY DATE: Entered STN: 20040520

Last Updated on STN: 20040520

AB Scientific data from the past decade have proved that the age of 35 years

is not an obligatory border at which to stop taking oral contraceptives (OCs). Combined OC formulations (COCs) are safe and effective for healthy women up to the age of the menopause. The use of OCs in women who do not smoke does not result in an increased risk of cardiovascular disease. Since the risk of thromboembolism increases with age and the level of obesity in women of 40 and over, it is wise to prescribe the lowest available dose of ethinyl-estradiol in the COCs. Some authors prefer levonorgestrel to any third-generation progestogen in COCs, but the excess risk of venous thromboembolism associated with the use of third-generation products can be balanced by the reduced risk of myocardial infarction associated with the same products. When OCs are considered for perimenopausal women, it is important to take into account progestogen-only pills. In consequence of the reduced fecundity, these have a better contraceptive efficacy in this age group than in women aged below 35 years. Their only important possible adverse effect is an unpredictable bleeding pattern; further, they do not alleviate climacteric symptoms if these are present In such cases, progestogen-only pills can be combined with cyclic hormone replacement therapy.

L3 ANSWER 25 OF 36 EMBASE COPYRIGHT (c) 2006 Elsevier B.V. All rights reserved on STN

ACCESSION NUMBER: 2004144548 EMBASE

TITLE: Avoiding Menstruation: A Review of Health and Lifestyle

Issues.

AUTHOR: Henzl M.R.; Polan M.L.

CORPORATE SOURCE: Dr. M.R. Henzl, Department of Obstetrics, Stanford Univ.

School of Medicine, Stanford, CA 94305-5317, United States Journal of Reproductive Medicine for the Obstetrician and

SOURCE: Journal of Reproductive Medicine for the Obstetric Gynecologist, (2004) Vol. 49, No. 3, pp. 162-174.

Refs: 49

ISSN: 0024-7758 CODEN: JRPMAP

COUNTRY: United States

DOCUMENT TYPE: Journal; General Review FILE SEGMENT: 003 Endocrinology

010 Obstetrics and Gynecology

030 Pharmacology

037 Drug Literature Index 038 Adverse Reactions Titles

LANGUAGE: English SUMMARY LANGUAGE: English

ENTRY DATE: Entered STN: 20040506

Last Updated on STN: 20040506

AΒ This article (1) reviews the decades-long history of short-term dosing regimens delaying the onset of expected, spontaneous menses or withdrawal bleeding in oral contraceptive users up to 20 days; (2) outlines treatment schedules that suppress menstrual bleeding for several months; and (3) evaluates the recently approved extended dosing regimen of 3 months' duration. For single-term postponement of normal menses, estrogen-progestogen combinations can be employed, starting about 7 days after ovulation. Oral contraceptive users can skip the 7-day pill-free period and continue with the active pills in the next package. The main focus of this review is the development of extended dosing schedules that result in cycles lasting 7 weeks up to several months and reduce the number of periods of bleeding and menstrual discomfort. Recently a dosing schedule was introduced into clinical use consisting of ethinyl estradiol, 30 μg , plus levonorgestrel, 150 $\mu g/d$, for 84 days, followed by 7 days of placebo. The pregnancy rate was < 1% for compliant women and 1.5% for all participants. A monophasic 21 + 7-day combination using the same daily doses had slightly higher pregnancy The discontinuation rate for unscheduled bleeding and spotting was higher with extended dosing than with the conventional, 21 + 7 schedule.

L3 ANSWER 26 OF 36 USPATFULL on STN ACCESSION NUMBER: 2005:287481 USPATFULL

Management of breakthrough bleeding in extended TITLE:

hormonal contraceptive regimens

Sachse, Andreas, Berlin, GERMANY, FEDERAL REPUBLIC OF INVENTOR(S):

KIND DATE NUMBER -----US 2005250747 A1 20051110 US 2005-118779 A1 20050502 (11) PATENT INFORMATION: APPLICATION INFO.:

NUMBER DATE _____ US 2004-566443P 20040430 (60) US 2004-575024P 20040528 (60) US 2004-577199P 20040607 (60) US 2004-638380P 20041227 (60) US 2005-660068P 20050310 (60) PRIORITY INFORMATION:

DOCUMENT TYPE: Utility FILE SEGMENT: APPLICATION

LEGAL REPRESENTATIVE: MILLEN, WHITE, ZELANO & BRANIGAN, P.C., 2200 CLARENDON

BLVD., SUITE 1400, ARLINGTON, VA, 22201, US

NUMBER OF CLAIMS: EXEMPLARY CLAIM: 1 LINE COUNT: 715

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

The present invention relates to a flexible extended use regimen for a hormonal contraceptive useful to manage bleeding problems associated with fixed extended use of hormonal contraceptives and to a

pharmaceutical package containing the respective hormonal contraceptive.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 27 OF 36 USPATFULL on STN

ACCESSION NUMBER: 2005:172611 USPATFULL

TITLE: System and method for visually presenting digital

patient information for future drug use resulting from

dosage alteration

Peterson, Per A., Basking Ridge, NJ, UNITED STATES INVENTOR(S):

Myers, Scott D., Skillman, NJ, UNITED STATES Shen-Hsieh, Angela, Cambridge, MA, UNITED STATES Schindler, Mark B., Cambridge, MA, UNITED STATES Alligood, Jacqueline, Flemington, NJ, UNITED STATES

NUMBER KIND DATE -----US 2005149362 A1 20050707 US 2003-748081 A1 20031230 (10) PATENT INFORMATION: APPLICATION INFO.:

DOCUMENT TYPE: Utility APPLICATION FILE SEGMENT:

LEGAL REPRESENTATIVE: Greenberg Traurig, LLP, 885 Third Avenue, New York, NY,

10022, US

NUMBER OF CLAIMS: 60 NUMBER OF DRAWINGS: 17 Drawings: 17079 EXEMPLARY CLAIM:

17 Drawing Page(s)

AΒ This invention provides a system and method of visually presenting future drug use in a subject where the subject's usage of a drug is altered. The invention comprises selecting a drug associated with Digital Patient Information (DPI). Risk periods associated with the

future drug usage period are also displayed.

ANSWER 28 OF 36 USPATFULL on STN

ACCESSION NUMBER: 2005:165934 USPATFULL

Methods of hormonal treatment utilizing contraceptive TITLE:

INVENTOR(S):

regimens with continuous estrogen administration Bell, Robert G., Palm Harbor, FL, UNITED STATES Ben-Maimon, Carole S., Merion, PA, UNITED STATES Iskold, Beata, Livingston, NJ, UNITED STATES Bronnenkant, Lance J., Snyder, NY, UNITED STATES Hait, Howard, Wilmington, DE, UNITED STATES Reape, Kathleen Z., Bryn Mawr, PA, UNITED STATES

PATENT INFORMATION: APPLICATION INFO.:

US 2005143359 A1 20050630 US 2004-892404 A1 20040716 (10)

NUMBER DATE

PRIORITY INFORMATION:

US 2003-487257P 20030716 (60)

DOCUMENT TYPE: FILE SEGMENT:

Utility APPLICATION

LEGAL REPRESENTATIVE:

STERNE, KESSLER, GOLDSTEIN & FOX PLLC, 1100 NEW YORK

AVENUE, N.W., WASHINGTON, DC, 20005, US

NUMBER OF CLAIMS: EXEMPLARY CLAIM:

68

NUMBER OF DRAWINGS:

10 Drawing Page(s)

LINE COUNT:

3400

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention provides contraceptive regimens in which a female is administered a combined dosage form of estrogen and progestin followed by a period of administration of estrogen. The disclosed contraceptive regimens can be administered to a female as a method of providing non-contraceptive benefits.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 29 OF 36 USPATFULL on STN

ACCESSION NUMBER:

2005:87025 USPATFULL

TITLE:

Transdermal and topical administration of drugs using

basic permeation enhancers

INVENTOR(S):

Hsu, Tsung-Min, San Diego, CA, UNITED STATES
Gricenko, Nicole T., San Diego, CA, UNITED STATES
Hickey, Alan T. J., San Diego, CA, UNITED STATES
Jacobson, Eric C., San Diego, CA, UNITED STATES
LoBello, Rose C., San Diego, CA, UNITED STATES
Obara, Jane, San Diego, CA, UNITED STATES
Luo, Eric C., Plano, TX, UNITED STATES

NUMBER	KIND	DATE

PATENT INFORMATION: APPLICATION INFO.: RELATED APPLN. INFO.: US 2005074487 A1 20050407 US 2004-863432 A1 20040607 (10)

Continuation-in-part of Ser. No. US 2002-176952, filed on 21 Jun 2002, ABANDONED Continuation-in-part of Ser. No. US 2003-675603, filed on 29 Sep 2003, PENDING Division of Ser. No. US 2002-176265, filed on 19 Jun 2002, GRANTED, Pat. No. US 6673363 Continuation-in-part of Ser. No. US 2002-175769, filed on 19 Jun 2002, ABANDONED Continuation-in-part of Ser. No. US 2002-175721, filed on 19 Jun 2002, ABANDONED Continuation-in-part of Ser. No. US 2002-175682, filed on 19 Jun 2002, PENDING Continuation-in-part of Ser. No. US 2002-176264, filed on 19 Jun 2002, PENDING Continuation-in-part of Ser. No. US 2002-175681, filed on 19 Jun 2002, PENDING Continuation-in-part of Ser. No. US 2001-972008, filed on 4 Oct 2001, GRANTED, Pat.

No. US 6582724 Continuation-in-part of Ser. No. US

2000-738410, filed on 14 Dec 2000, GRANTED, Pat. No. US

6586000 Continuation-in-part of Ser. No. US 2000-569889, filed on 11 May 2000, ABANDONED

Continuation-in-part of Ser. No. US 1999-465098, filed on 16 Dec 1999, ABANDONED Continuation-in-part of Ser. No. US 2000-738395, filed on 14 Dec 2000, GRANTED, Pat. No. US 6719997 Continuation-in-part of Ser. No. US

2000-607892, filed on 30 Jun 2000, ABANDONED

DOCUMENT TYPE: FILE SEGMENT:

Utility APPLICATION

LEGAL REPRESENTATIVE:

REED INTELLECTUAL PROPERTY LAW GROUP, 800 MENLO AVENUE,

SUITE 210, MENLO PARK, CA, 94025

NUMBER OF CLAIMS: EXEMPLARY CLAIM:

1

LINE COUNT:

4435

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

Methods are provided for enhancing the permeability of skin or mucosal tissue to topical or transdermal application of pharmacologically or cosmeceutically active agents. The methods entail the use of a base in order to increase the flux of the active agent through a body surface while minimizing the likelihood of skin damage, irritation or sensitization. The permeation enhancer can be an inorganic or organic

base. Compositions and transdermal systems are also described.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 30 OF 36 USPATFULL on STN

ACCESSION NUMBER:

2005:38084 USPATFULL

TITLE:

Process of making isomers of norelgestromin

and methods using the same

INVENTOR(S):

Tuba, Zoltan, Budapest, HUNGARY Maho, Sandor, Budapest, HUNGARY Keseru, Gyorgy, Telki, HUNGARY Kozma, Jozsef, Budapest, HUNGARY Horvath, Janos, Budapest, HUNGARY Balogh, Gabor, Budapest, HUNGARY

PATENT ASSIGNEE(S):

Richter Gedeon Vegyeszeti Gyar Rt. (non-U.S.

corporation)

NUMBER	KIND	DATE	
US 2005032764	A1	20050210	
119 2004-070710	7.1	20040630	(10)

PATENT INFORMATION: APPLICATION INFO.:

US 2004-879710 AΙ 20040630 (10)

	NUMBER	DATE
HU	2003-P1981	20030630
HU	2003-P1982	20030630

DOCUMENT TYPE:

PRIORITY INFORMATION:

Utility APPLICATION

FILE SEGMENT: LEGAL REPRESENTATIVE:

STERNE, KESSLER, GOLDSTEIN & FOX PLLC, 1100 NEW YORK

AVENUE, N.W., WASHINGTON, DC, 20005

NUMBER OF CLAIMS:

42

EXEMPLARY CLAIM: NUMBER OF DRAWINGS:

1 Drawing Page(s)

LINE COUNT: 1757

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

The invention is directed to a process of preparing substantially pure d-(17α)-13-ethyl-17-hydroxy-18,19-dinorpregn-4-ene-20-yn-3-one-3Eand -3Z-oxime isomers, as well as a process for the synthesis of the mixture of isomers and the pure isomers. The invention also relates to substantially pure $d-(17\alpha)-13-ethyl-17-hydroxy-18,19-dinorpregn-4$ ene20-yn-3-one-3E-oxime and substantially pure $d-(17\alpha)-13-ethyl-17$ hydroxy-18,19-dinorpregn-4-ene-20-yn-3-one-3Z-oxime isomer. Further

aspects of the invention include a composition comprising substantially pure $d-(17\alpha)-13-ethyl-17-hydroxy-18,19-dinorpregn-4-ene20-yn-3-one-$ 3E-oxime or substantially pure $d-(17\alpha)-13-ethyl-17-hydroxy-18,19$ dinorpregn-4-ene-20-yn-3-one-3Z-oxime isomer, and methods of treatment using said compositions.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 31 OF 36 USPATFULL on STN

ACCESSION NUMBER: 2005:38083 USPATFULL

Process for the synthesis of high purity TITLE:

D-(17a)-13-ethyl-17-hydroxy-18,19-dinorpregn-4-ene-20-

yn-3-one oxime

INVENTOR(S):

Tuba, Zoltan, Budapest, HUNGARY Maho, Sandor, Budapest, HUNGARY Kiss, Janos, Budapest, HUNGARY

Magyari, Endrene, Albertirsa II, HUNGARY

Terdy, Laszlo, Budapest, HUNGARY

NUMBER KIND DATE -----US 2005032763 A1 20050210 US 2004-879708 A1 20040630 (10) PATENT INFORMATION: APPLICATION INFO.:

NUMBER DATE -----HU 2003-P1981 20030630 HU 2003-P1982 20030630 PRIORITY INFORMATION:

DOCUMENT TYPE: Utility FILE SEGMENT: APPLICATION

STERNE, KESSLER, GOLDSTEIN & FOX PLLC, 1100 NEW YORK LEGAL REPRESENTATIVE:

AVENUE, N.W., WASHINGTON, DC, 20005

NUMBER OF CLAIMS: 18 EXEMPLARY CLAIM: 1 LINE COUNT: 1273

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

The invention relates to a process for the synthesis of $d-(17\alpha)-13-ethyl-17-hydroxy-18,19-dinorpregn-4-ene-20-yn-3-one$ oxime (also known as norelgestromin) via acetylation of d-norgestrel at position 17; oximation of the oxo group at position 3 of the obtained $d-(17\alpha)-13-ethyl-17-(acetyloxy)-18,19-dinorpregn-4$ ene-20-yn-3-one; and then hydrolyzing the acetyloxy group at position 17 of the obtained $d-(17\alpha)-13-ethyl-17-(acetyloxy)-18,19-dinorpregn-4$ ene-20-yn-3-oxime derivative, thereby obtaining norelgestromin

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 32 OF 36 USPATFULL on STN

ACCESSION NUMBER: 2004:280961 USPATFULL

TITLE: Transdermal and topical administration of drugs using

basic permeation enhancers

INVENTOR(S): Hsu, Tsung-Min, San Diego, CA, UNITED STATES

Gricenko, Nicole T., San Diego, CA, UNITED STATES
Hickey, Alan T. J., San Diego, CA, UNITED STATES
Jacobson, Eric C., San Diego, CA, UNITED STATES
LOBello, Rose C., San Diego, CA, UNITED STATES
Obara, Jane, San Diego, CA, UNITED STATES

Luo, Eric C., Plano, TX, UNITED STATES

NUMBER KIND DATE -----US 2004220262 A1 20041104 US 2004-860887 A1 20040603 (10) PATENT INFORMATION: APPLICATION INFO.:

RELATED APPLN. INFO.: Division of Ser. No. US 2002-177436, filed on 20 Jun

2002, PENDING Continuation-in-part of Ser. No. US 2001-972008, filed on 4 Oct 2001, GRANTED, Pat. No. US

6582724 Continuation-in-part of Ser. No. US

2000-738410, filed on 14 Dec 2000, GRANTED, Pat. No. US

6586000 Continuation-in-part of Ser. No. US 2000-569889, filed on 11 May 2000, ABANDONED

Continuation-in-part of Ser. No. US 1999-465098, filed on 16 Dec 1999, ABANDONED Continuation-in-part of Ser. No. US 2000-738395, filed on 14 Dec 2000, GRANTED, Pat. No. US 6719997 Continuation-in-part of Ser. No. US

2000-607892, filed on 30 Jun 2000, ABANDONED

DOCUMENT TYPE: Utility FILE SEGMENT: APPLICATION .

LEGAL REPRESENTATIVE: REED & EBERLE LLP, 800 MENLO AVENUE, SUITE 210, MENLO

PARK, CA, 94025

NUMBER OF CLAIMS: EXEMPLARY CLAIM: 1 LINE COUNT: 4380

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

Methods are provided for enhancing the permeability of skin or mucosal tissue to topical or transdermal application of pharmacologically or cosmeceutically active agents. The methods entail the use of a base in order to increase the flux of the active agent through a body surface while minimizing the likelihood of skin damage, irritation or

sensitization. The permeation enhancer can be an inorganic or organic

base. Compositions and transdermal systems are also described.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 33 OF 36 USPATFULL on STN

2004:280851 USPATFULL ACCESSION NUMBER:

TITLE: Methods of hormonal treatment utilizing extended cycle

contraceptive regimens

INVENTOR(S): Ben-Maimon, Carole S., Merion, PA, UNITED STATES

Hait, Howard, Wilmington, DE, UNITED STATES

Reape, Kathleen Z., Bryn Mawr, PA, UNITED STATES

Bronnenkant, Lance J., Synder, NY, UNITED STATES

NUMBER DATE KIND PATENT INFORMATION:

US 2004220152 A1 20041104 US 2004-837268 A1 20040503 (10) APPLICATION INFO.:

> NUMBER DATE

US 2003-524081P 20031124 (60) US 2003-467172P 20030502 (60) PRIORITY INFORMATION:

DOCUMENT TYPE: Utility FILE SEGMENT: APPLICATION

LEGAL REPRESENTATIVE: STERNE, KESSLER, GOLDSTEIN & FOX PLLC, 1100 NEW YORK

AVENUE, N.W., WASHINGTON, DC, 20005

NUMBER OF CLAIMS: 148 EXEMPLARY CLAIM:

NUMBER OF DRAWINGS: 2 Drawing Page(s)

LINE COUNT: 2475

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

The present invention provides extended cycle contraceptive regimens in which a female is administered a combined dosage form of estrogen and progestin. The disclosed extended cycle contraceptive regimens can be administered to a female as a method of providing non-contraceptive

benefits.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 34 OF 36 USPATFULL on STN

ACCESSION NUMBER: 2004:64400 USPATFULL

TITLE: Compositions and methods for reduction of inflammatory

symptoms and/or biomarkers in female subjects INVENTOR(S): Dreon, Darlene M., Menlo Park, CA, UNITED STATES

Phinney, Stephen Dodge, Elk Grove, CA, UNITED STATES

KIND NUMBER DATE -----US 2004048919 A1 US 2003-612118 A1 PATENT INFORMATION: 20040311

APPLICATION INFO.: 20030702 (10)

> DATE NUMBER ______

US 2002-393550P 20020702 (60) US 2003-461325P 20030408 (60) PRIORITY INFORMATION:

DOCUMENT TYPE: Utility FILE SEGMENT: APPLICATION

GALILEO PHARMACEUTICALS, INC., (PREVIOUSLY GALILEO LEGAL REPRESENTATIVE:

LABORATORIES, INC.), 5301 PATRICK HENRY DRIVE, SANTA

CLARA, CA, 95954

NUMBER OF CLAIMS: EXEMPLARY CLAIM: 1

NUMBER OF DRAWINGS: 3 Drawing Page(s)

LINE COUNT: 2282

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

Medicaments and methods for the treatment and/or amelioration of certain inflammatory symptoms related to premenstrual syndrome (PMS), premenstrual dysphoric disorder (PMDD), perimenopause, menopause, endometriosis, post-partum depression, or administration of hormonal contraceptives are described herein. Medicaments of the invention comprise a tocopherol, an omega-3 polyunsaturated fatty acid, such as docosahexaenoic acid (DHA), or omega-9 polyunsaturated fatty acid, optionally, a flavonoid, and, optionally, a mineral, such as magnesium. Methods for treating or ameliorating such symptoms and methods for reducing elevated CRP and/or white blood cell (WBC) associated with such conditions using medicaments of the invention are also described.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 35 OF 36 USPATFULL on STN

ACCESSION NUMBER: 2003:180349 USPATFULL

TITLE: Transdermal and topical administration of drugs using

basic permeation enhancers

INVENTOR(S): Hsu, Tsung-Min, San Diego, CA, UNITED STATES

Gricenko, Nicole T., San Diego, CA, UNITED STATES Hickey, Alan T.J., San Diego, CA, UNITED STATES Jacobson, Eric C., San Diego, CA, UNITED STATES LoBello, Rose C., San Diego, CA, UNITED STATES

Obara, Jane, San Diego, CA, UNITED STATES Luo, Eric C., Plano, TX, UNITED STATES

		NUMBER	KIND	DATE	
PATENT INFORMATION:	US	2003124176	A1	20030703	
APPLICATION INFO.:	US	2002-176952	A1	20020621	(10)

RELATED APPLN. INFO.: Continuation-in-part of Ser. No. US 2001-972008, filed

on 4 Oct 2001, PENDING Continuation-in-part of Ser. No.

US 2000-738410, filed on 14 Dec 2000, PENDING

Continuation-in-part of Ser. No. US 2000-569889, filed on 11 May 2000, PENDING Continuation-in-part of Ser. No. US 1999-465098, filed on 16 Dec 1999, ABANDONED Continuation-in-part of Ser. No. US 2000-738395, filed on 14 Dec 2000, PENDING Continuation of Ser. No. US

2000-607892, filed on 30 Jun 2000, ABANDONED

DOCUMENT TYPE:

Utility APPLICATION

FILE SEGMENT: LEGAL REPRESENTATIVE:

REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO

PARK, CA, 94025

NUMBER OF CLAIMS: EXEMPLARY CLAIM:

72 1 4440

LINE COUNT:

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

Methods are provided for enhancing the permeability of skin or mucosal tissue to topical or transdermal application of pharmacologically or cosmeceutically active agents. The methods entail the use of a base in order to increase the flux of the active agent through a body surface while minimizing the likelihood of skin damage, irritation or sensitization. The permeation enhancer can be an inorganic or organic base. Compositions and transdermal systems are also described.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

ANSWER 36 OF 36 USPATFULL on STN

ACCESSION NUMBER:

2003:152375 USPATFULL

TITLE:

Transdermal and topical administration of drugs using

basic permeation enhancers

INVENTOR(S):

Hsu, Tsung-Min, San Diego, CA, UNITED STATES Gricenko, Nicole T., San Diego, CA, UNITED STATES Hickey, Alan T. J., San Diego, CA, UNITED STATES Jacobson, Eric C., San Diego, CA, UNITED STATES LoBello, Rose C., San Diego, CA, UNITED STATES Obara, Jane, San Diego, CA, UNITED STATES

Luo, Eric C., Plano, TX, UNITED STATES

NUMBER	KIND	DATE

PATENT INFORMATION: APPLICATION INFO.:

US 2003104041 20030605 A1

US 2002-177436 A1 20020620 (10)

RELATED APPLN. INFO.:

Continuation-in-part of Ser. No. US 2001-972008, filed on 4 Oct 2001, PENDING Continuation-in-part of Ser. No.

US 2000-738410, filed on 14 Dec 2000, PENDING

Continuation-in-part of Ser. No. US 2000-569889, filed on 11 May 2000, PENDING Continuation-in-part of Ser. No. US 1999-465098, filed on 16 Dec 1999, PENDING Continuation-in-part of Ser. No. US 2000-738395, filed on 14 Dec 2000, PENDING Continuation-in-part of Ser. No. US 2000-607892, filed on 30 Jun 2000, ABANDONED

DOCUMENT TYPE: FILE SEGMENT:

Utility APPLICATION

LEGAL REPRESENTATIVE:

REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO

PARK, CA, 94025

NUMBER OF CLAIMS: EXEMPLARY CLAIM:

LINE COUNT:

4474

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

Methods are provided for enhancing the permeability of skin or mucosal tissue to topical or transdermal application of pharmacologically or cosmeceutically active agents. The methods entail the use of a base in order to increase the flux of the active agent through a body surface

while minimizing the likelihood of skin damage, irritation or

sensitization. The permeation enhancer can be an inorganic or organic

base. Compositions and transdermal systems are also described.

CAS INDEXING IS AVAILABLE FOR THIS PATENT.